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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/400,365	09/20/1999	FADY T. CHARBEL	76461	3361

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SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER

CHOI, KYLE JAEHUN

ART UNIT	PAPER NUMBER
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3623

DATE MAILED: 10/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/400,365

Applicant(s)

CHARBEL ET AL.

Examiner

Kyle J. Choi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 and 52-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 10-18, 20-28 and 52-55 is/are rejected.
- 7) ☒ Claim(s) 8, 9 and 19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 September 1999 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. The following is a Final Office Action in response to the communication filed July 23, 2002. By the amendment:

Claims 1, 5, 6, 8-12, 15-17, 19-28, 52, 55 been amended.
No claims have been added or cancelled.

Claims 1-28, 52-55 are now pending in this application and have been examined on the merits as discussed below.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It was not executed in accordance with either 37 CFR 1.66 or 1.68.

In particular, Lewis Sadler did not execute the Oath/Declaration (i.e., no signature).

Response to Amendment

3. Applicant's amendment to the claims has overcome the previous objections and rejections under §112, first and second paragraphs. Accordingly, these objections and rejections are hereby withdrawn. However, the amendment to the above-

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identified claims raise new objections and rejections under §112, second paragraph, as explained below.

4. Additionally, applicant is respectfully reminded about the proper procedure for making amendment to the claims. 37 C.F.R. §1.121(c)(1)(i) specifically requires, in the **CLEAN VERSION** of the claims, parenthetical expression after a claim number stating the status of the claim *including how many times the claim has been amended* (e.g., once amended, twice amended, three-times amended, etc.). Moreover, §1.121(c)(1)(ii) requires that the MARKED-UP VERSION also have the same and BOTH VERSIONS must correspond.

In the present case, applicant has failed to indicate ANY parenthetical expression after the claim number in the CLEAN VERSION. The parenthetical expression in the MARKED-UP VERSION includes parenthetical expressions to indicate which claims were amended but fails to indicate how many times the claims were amended. Consequently, the parenthetical expressions between the CLEAN VERSION and the MARKED-UP VERSION are therefore inconsistent. Applicant is respectfully reminded that the proper procedure for amendment is **required** and any such deficiencies in future correspondence will be considered as being "Non-Responsive".

Response to Arguments

5. Applicant's arguments have been fully considered but they are found to be persuasive in part and not persuasive in part. In particular, applicant's main argument with respect to the amended claims is directed to the fact that none of the art of record allegedly teaches "correcting a circulatory model based upon the calculated and measured flows". (Response: Page 9, lines 22-23) This correcting step apparently involves "multiplying a vessel resistance value in the model by a ratio of the calculated and measured flows." (Response: Page 9, lines 19-20)

This examiner agrees with the allegation that the art of record, individually or in combination, fails to teach multiplying a vessel resistance value in a circulation model by a ratio of the calculated and measured flows. However, applicant is respectfully reminded that none of the claims, **as currently recited**, claim such a feature. For example, claim 1 as amended now recites a step of "correcting the simulation based upon calculated and measured flows" (emphasis added). There is no recitation of modifying the circulation model or is there any recitation that the flow resistance of the model is corrected based on the ratio of measured and calculated values.

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As currently recited, ANY parameter of ANY part of the simulation can be adjusted based on the measured and calculated flow in ANY way to meet the limitations of claim 1. In this context, the 1996 presentation abstract (previously dubbed Charbel #1) teaches such "remodeling procedures" and therefore does have a suggestion for correcting the initial model based on observed actual performance. The same recitation is found in each of the other independent claims (claims 12 and 23).

It is respectfully submitted that ANY validation procedure includes such a step in the simulation arts. That is to say, the purpose of a typical "validation" procedure in the art of computer simulation is to verify that the computer model is reliable. To that end, one of ordinary skill in the art will take the predicted results (i.e., the simulation results from the model) and compare them to actual results (i.e., measured results from the real world) to determine how well the model performed in the simulation. Based on this information, the various portions of the model and/or the simulation procedure is "tweaked" to determine the under- or over-estimated parameters based on the actual measurements to more closely model the real world counterpart.

Although the claims are interpreted in light of the specification, limitations from the specification are not read

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into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). This is because applicant always has the opportunity to amend the claims during prosecution, and broad interpretation by the examiner reduces the possibility that the claim, once issued will be interpreted more broadly than is justified. *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969). During patent examination, the pending claims must be given the "broadest reasonable interpretation consistent with the specification." See MPEP §2111.

The only claims currently pending that are closest to the argued limitation are claims 8 and 19. These claims specifically recites that the correction is made to the flow resistance based on the ratio of the calculated and measured flows. This limitation is significantly specific that is not readily apparent in the art of record. Hence, these claims have been indicated below as being objected to for depending on rejected base claims but would be allowable if the dependency is corrected either by rewriting the dependent claims as independent claims or by incorporating the limitation into the independent claims.

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Drawings

6. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the feature of correcting the flow resistance of the simulation/model based on a ratio of measured and calculated flow as now recited in claims 8 and 19 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. **The objection to the drawings will not be held in abeyance.**

Claim Objections

7. **Claim 8** is objected to because of the following informalities:

a. Claim 8 ends with two periods (.) .

Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. **Claims 12-28, 54 and 55** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. **As to claim 12**, claim 12, as amended, now recites that a computerized simulation model "...calculates blood flows...." It is vague and indefinite as to how a "model" performs the calculation. The "model" as disclosed in the specification of the present application is a series of mathematical expressions implemented by computer code to merely "describe" the circulatory system of a patient. The model it and of itself does not have the capability of performing any calculations. As it is typically the case in any simulation application, it is the "simulator" that performs the calculations based on the model. One possible suggestion for overcoming this rejection is to recite:

means for calculating blood flows in the circulatory system when the model is forced with a forcing function.

b. **As to claim 23**, claim 23, as amended, now recites that the model **includes** "an adaptation module" and "a

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correction module". As discussed above, the model as disclosed in the specification is a computer implemented mathematical expression for describing a circulatory system of a patient. It is not capable of "including" an adaptation module or a correction module in the manner recited. Again, one possible suggestion for overcoming this rejection is to recite the adaptation module and the correction module as separate components of the simulation system (as opposed to components of the model).

c. As to claims 10 and 21, these claims, as amended, now recites that the simulation is forced with "a flow measurement obtained from the living subject". The purpose of the simulation as disclosed in the application is to obtain a model that will most closely simulate the real world counterpart. To that end, it is vague and indefinite as to what the purpose of the simulation and development of a model would be if the simulation is going to be forced to use the measured flow anyway.

d. As to the dependent claims, these claims are rejected due to their dependence to deficient base claims 12 and 23. Any amendments to claims 12 and 23

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to overcome the above rejections would necessarily overcome the rejections to the dependent claims.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Before setting forth the rejection below, a short discussion of the art is in order. Applicant's IDS has set forth the following references that this examiner considers to be pertinent in the present application:

a. *"Predictive Value of a Computerized Model for the Cerebral Circulation,"* (Poster Abstract) a presentation apparently made at the 44th Annual Meeting of Congress of Neurological Surgeons in October of 1994 [previously dubbed as "Charbel #2" in the prior Office Action]; and

b. *"Validation and Clinical Potential of a Computerized Model of the Cerebral Circulation,"* (Poster Abstract) a presentation apparently made at the 1st Annual Meeting of the Joint Section on Cerebrovascular Surgery of the

American Association of Neurological Surgeons and the Congress of Neurological Surgeons in January of 1996 [previously dubbed as "Charbel #1" in the prior Office Action.

Looking at the authors of these presentations, it is apparent that two of the named inventors in the present application were working on the materials in at least two of these presentations more than a year prior to the filing of the provisional application from which the current application depends (i.e., February 3, 1998). Furthermore, it is apparent from reading the abstracts that the work presented in 1996 [previously dubbed Charbel #1] was an extension of the work presented in 1994 [previously dubbed Charbel #2]. More specifically, the abstract from the 1994 presentation states, in part, "[W]e find the predictive value of this model promising. *In vivo* validation is currently underway." Unsurprisingly, the presentation made in 1996 is a "direct *in vivo* validation of the [computer] model." Though the authors (i.e., the "inventive entities") of these presentations are not exactly the same, three of the listed authors remained consistent (i.e., Charbel, Clarke, Ausman). Consequently, these two presentations are hereby considered to be one "teaching" (i.e., the 1996

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validation procedures used the computer modeling disclosed in the 1994 presentation).

Examiner's attempt to verify this inference in a Rule 105 request in the previous Office Action did not produce any more guidance from the applicant. However, due to the direct correlation between the abstracts themselves, it is this examiner's belief that the two presentations are directed to the same computer simulation model disclosed in the 1994 presentation. Thus, it is on this proposition that the following rejection is based. *For convenience, these two presentations will be referred to simply as "Charbel et al." hereinafter.*

12. Claims 1-4, 10-14, 20, 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by *Charbel et al.*

Charbel et al. discloses a computer program and method for simulating surgical procedures on a patient that alters circulation systems. The computer program is for any multivesselled network configuration, including the Circle of Willis, as well as surgical anastomoses supplied to the vessels. The computer program applies one-dimensional, explicit, finite-difference algorithm based on a conservation of mass equation, a Navier-Stokes momentum

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equation, and an equation of state relating local pressure to size of artery to obtain computerized model of the cerebral circulation and its concurrent simulation results. The simulation includes forcing the model by one or more pressure- or flow-time signatures. (1994 presentation abstract: p. 166, §27.) The computerized model is specifically tailored to "any distensible vessels of various shapes, lengths and configurations" that is "reconfigured to include stenoses, bypasses and natural or imposed anatomoses" (i.e., surgical perturbations) thereby "reproducing each patient's individual anatomy." (1996 presentation abstract: p. 113, col. 1, ¶1.) The calculated flow and the measured flow are then compared to validate the accuracy of the computer model to the actual patient including a "remodeling procedure" (i.e., to correct for any discrepancies observed between the predicted and actual values). (1996 presentation abstract: p. 113, col. 2, lns. 11-15.)

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. **Claims 5-7, 25-28** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Charbel et al.**, as discussed above, in view of either **Karplus** or **Foutrakis**, both previously cited by the examiner.

Charbel et al. discloses the recited invention as discussed above. However, Charbel et al. does not teach how the specific parameters are collected, i.e., obtaining boundary measurements (e.g., diameter of the vessel and tracing ends of the vessel) using image/pixel analysis to determine the measurements of the vessels of the living subject.

Karplus, previously cited and applied in the prior Office Action, teaches obtaining boundary and cross-section information of specified vessels using MRI technology for the purpose of inputting the gathered information into a circulation simulator for generating a specific simulation result for a specific patient. (p. 38, §3.2)

Foutrakis, previously cited and applied in the prior Office Action, teaches obtaining boundary and cross-section information

of specified vessels using MRI technology for the purpose of inputting the gathered information into a circulation simulator for generating a specific simulation result for a specific patient. (Abstract; p. 4; Figure 7; p. 12)

It would have been obvious for one of ordinary skill in the art at the time of the invention to have used Magnetic Resonance Imaging technology to obtain the specific parameters of a specific vessel as taught by Karplus and Foutrakis to be used in the simulation as taught by Charbel et al. because Charbel et al. already teaches tailoring a simulation using specific parameters of a vessel of a patient and Karplus/Foutrakis both teach it is well known to obtain such information using MRI technology in the manner recited.

15. Claims 15-18, 52, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Charbel et al.*, as applied above, in view of *Charbel et al. (1997 presentation abstract)*, cited by the Applicant.

As to claims 15, 52, and 55, Charbel et al. discloses the recited invention as discussed above. In particular, Charbel et al. specifically teaches that direct flow measurements were obtained. Charbel et al. does not specifically teach that

PCMRA (Phase Contract Magnetic Resonance Angiography) flow measurement techniques were used.

Charbel et al. ("Phase Contract MR Flow Measurement System Using Volumetric Flow Constrained Image Interpolation and Color Coded Image Visualization", Poster Abstract of a presentation made at the 47th Annual Meeting of Congress of Neurological Surgeons in September/October of 1997) discloses that PCMRA was available in 1997 to measure blood flow in a patient. Moreover, various other non-intrusive flow measurement systems were already available at the time the invention was made (e.g., Doppler). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used PCMRA to obtain the flow measurement since it was known to one of ordinary skill in the art that non-invasive measurement techniques were available, and PCMRA was purported to provide a more accurate flow measurement result than the other options as taught in Charbel et al. (1997 presentation abstract).

As to claims 16-18, Charbel et al. (1997 presentation) teaches that PCMRA can also be used to obtain cross-section measurements as well. (1997 presentation abstract: p. 377, Introduction, lines 4-6). As to localizing and tracing three dimensional images of a vessel to obtain the measure, these steps are inherent in obtaining vessel measurements using image

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analysis (See Karplus and Foutrakis, cited and applied above) and therefore is considered to be inherent in Charbel et al. (1997 presentation abstract).

16. **Claims 53 and 54** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Charbel et al.** in view of either **Karplus** or **Ortega** ("*Predicting Cerebral Aneurysms with CFD*"), previously cited.

Charbel et al. teaches the recited invention as applied above. Though Charbel et al. teaches obtaining flow measurement (1996 presentation abstract), it does not teach that the flow measurements were obtained by Doppler measurements.

Karplus, as discussed above, teaches using Doppler flow measurements to correct and validate simulation results. (p. 40, col. 2, ¶4)

Ortega discloses using Doppler flow measurements to be used in Computational Fluid Dynamics simulation (CFD).

It would have been obvious for one of ordinary skill in the art at the time of the invention to have used Doppler technology to correct and validate simulation results as taught by Karplus/Ortega in the simulation as taught by Charbel et al. because Karplus/Ortega teaches that such correction/validation techniques using Doppler is well known to one of ordinary skill

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in the art to verify predicted results with actual results and non-invasive technology is always preferred.

Allowable Subject Matter

17. Claims 8-9 and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

In particular, none of the art of record, individually or in combination, teaches that the flow resistance of the simulation of the circulatory system model (claim 8) or the circulatory system model itself (claim 19) is corrected based on the ratio of the measured and calculated flows. Though the references of record suggests validating and correcting the circulatory model or the simulation based on measured flow values, which could possibly involve any number of parameters, none of the art of record specifically teach or suggest adjusting the flow resistance based on the ratio of the measured and calculated flow as recited in claims 8 and 19. Claim 9 is dependent on objected claim 8 and therefore the same reasons for allowance applies.

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Kyle J. Choi** whose telephone number is (703)306-5845. The examiner can normally be reached on Monday-Friday, 8:00am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Tariq Hafiz** can be reached on (703)305-9643.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the **Receptionist** whose telephone number is (703)308-1113.

Any response to this action should be mailed to:

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Washington D.C. 20231

or faxed to:

(703)305-7687 [Official communications; including
After Final communications labeled
"Box AF"]

(703)746-5548 [Informal/Draft communications, labeled
"PROPOSED" or "DRAFT"]

Hand delivered responses should be brought to Crystal Park
5, 2451 Crystal Drive, Arlington, VA, 7th floor receptionist.



KYLE J. CHOI
PRIMARY EXAMINER

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October 21, 2002